AMENDMENTS TO THE CLAIMS

The following listing of claims relaces all prior listings and versions of claims in this application.

Claims 1 to 33. (Cancelled)

34. (Currently Amended) A method for sustained transdermal delivery of a therapeutic or immunogenic agent, the method comprising: ~~a.~~ generating at least one micro-channel in a region on the skin of a subject; ~~b.~~ affixing a patch to the region of skin in which the at least one micro-channel is present, the patch comprising at least one drug reservoir layer, wherein the drug reservoir layer comprises a polymeric matrix and a pharmaceutical composition comprising a therapeutic or immunogenic peptide, polypeptide, or protein; and ~~c.~~ achieving a therapeutic blood concentration of the peptide, polypeptide, or protein for at least 6 hours.

35. (Original) The method according to claim 34, wherein the polymeric matrix is selected from the group consisting of hydrophilic biopolymers, hydrophilic synthetic polymers, derivatives and combinations thereof.

36. (Original) The method according to claim 35, wherein the biopolymer is selected from the group consisting of hydroxypropyl cellulose, carboxymethyl cellulose, hydroxyethyl cellulose, carrageenans, chitin, chitosan, alginates, collagens, gelatin, pectin, glycosaminoglycans (GAGs), proteoglycans, fibronectins, and laminins.

37. (Original) The method according to claim 36, wherein the biopolymer is selected from the group consisting of collagens and carrageenans.

38. (Original) The method according to claim 35, wherein the hydrophilic synthetic polymer is selected from the group consisting of polypropylene oxide, polyethylene oxide, polyoxyethylene-polyoxypropylene copolymers, polyvinylalcohol, polyurethanes.

39. (Original) The method according to claim 38, wherein the hydrophilic synthetic polymer is polyethylene oxide.

40. (Original) The method according to claim 34, wherein the drug reservoir layer is formulated in a form selected from a dry form, a semi-dry form, a hydrogel, and a solution.

41. (Currently Amended) The method according to claim 34, wherein the therapeutic or immunogenic ~~active~~ agent is selected from the group consisting of growth factors, hormones, cytokines, water-soluble drugs, antigens, antibodies, fragments and analogs thereof.

42. (Original) The method according to claim 34, wherein the active therapeutic or immunogenic agent is selected from the group consisting of insulin, proinsulin, follicle stimulating hormone, insulin like growth factor-1, insulin like growth factor-2, platelet derived growth factor, epidermal growth factor, fibroblast growth factors, nerve growth factor, transforming growth factors, tumor necrosis factor, calcitonin, parathyroid hormone, growth hormone, bone morphogenic protein, erythropoietin, hemopoietic growth factors, luteinizing hormone, glucagon, clotting factors, anti-clotting factors, atrial natriuretic factor, lung surfactant, plasminogen activators, bombesin, thrombin, enkephalinase, relaxin A-chain, relaxin B-chain, prorelaxin, inhibin, activin, vascular endothelial growth factor, hormone receptors, growth factor receptors, integrins, protein A, protein D, rheumatoid factors, neurotrophic factors, CD proteins, osteoinductive factors, immunotoxins, interferons, colony stimulating factors, interleukins (ILs), superoxide dismutase, T-cell receptors, surface membrane proteins, decay accelerating factor, viral antigens, transport proteins, homing receptors, addressing, regulatory proteins, analogs, derivatives and fragments thereof.

43. (Original) The method according to claim 42, wherein the therapeutic agent is growth hormone or insulin.

44. (Original) The method according to claim 34, wherein the drug reservoir layer comprises a collagen and human growth hormone.

45. (Original) The method according to claim 34, wherein the drug reservoir layer comprises a collagen and human insulin.

46. (Original) The method according to claim 34, wherein the drug reservoir layer comprises polyethylene oxide and human growth hormone.

47. (Original) The method according to claim 34, wherein the drug reservoir layer comprises polyethylene oxide and human insulin.

48. (Original) The method according to claim 34, wherein the drug reservoir layer comprises carrageenan and human growth hormone.

49. (Original) The method according to claim 34, wherein the drug reservoir layer comprises carrageenan and human insulin.

50. (Original) The method according to claim 34, wherein the patch further comprises at least one of the following layers: a backing layer, an adhesive, and a rate-controlling layer.

51. (Original) The method according to claim 34, wherein the pharmaceutical composition further comprises at least one component selected from the group consisting of protease inhibitors, stabilizers, anti-oxidants, buffering agents and preservatives.

52. (New) The method according to claim 34, wherein generating the at least one micro-channel is performed by an apparatus comprising: an electrode cartridge comprising a plurality of electrodes; and a main unit comprising a control unit, which is adapted to apply electrical energy to the electrodes when the electrodes are in vicinity of the skin, enabling ablation of stratum corneum in an area beneath the electrodes, thereby generating the at least one micro-channel.

53. (New) The method according to claim 52, wherein the electrode cartridge is adapted to generate a plurality of micro-channels of uniform shape and dimensions.

54. (New) The method according to claim 52, wherein the electrical energy is of radio frequency.